

REMARKS

Applicants submit herewith a copy of Offringa et al., "Extrachromosomal Homologous Recombination and Gene Targeting in Plant Cells After Agrobacterium Mediated Transformation," EMBO J. 9(10):3077-3084 (1990) ("Offringa"). Offringa was listed as Reference "CE" on the List of References Cited By Applicant, filed September 12, 2001. The U.S. Patent and Trademark Office ("USPTO") declined to consider Offringa on the ground that a copy of the reference had not been submitted to the USPTO. Offringa is cited on the accompanying PTO-1449 form. Applicants hereby request that the USPTO now consider Offringa, and initial and return the enclosed PTO-1449 form.

The objection to the drawings under 37 C.F.R. §§ 1.84(b), (e), (g), (h), (i), and (p), as identified in the Notice of Draftsperson's Patent Drawing Review of March 25, 2002, is respectfully traversed in view of the corrected formal drawings submitted herewith and described below.

Pursuant to 37 C.F.R. § 1.84(b), Figures 19-22, 27, and 31 have been amended to conform to the requirement that drawings of photographs be of sufficient quality so that all details in the photographs are reproducible in the printed patent.

Pursuant to 37 C.F.R. § 1.84(e), Figures 1A-15S and 17A have been amended to eliminate any erasures, alterations, overwritings, interlineations, folds, or copy machine marks.

Pursuant to 37 C.F.R. § 1.84(g), Figures 5B, 12A-14, 19, 21, 23, 29A, 29B, 30, 32, 33, and 35 have been amended to conform to acceptable margin size requirements.

Pursuant to 37 C.F.R. § 1.84(h), Figures 8, 9, 11B, and 28 have been amended to conform with the requirement that partial views be labeled separately and properly. Further, Figure 28 has been re-labeled as suggested by the Draftsperson in the "Comments" section of the March 25, 2002, Notice of Draftsperson's Patent Drawing Review.

Pursuant to 37 C.F.R. § 1.84(i), Figures 1A-14, 15A-15S, 23, and 24 have been amended to conform to the requirement that lines, numbers, and letters be uniformly thick and well-defined, clean, durable, and black.

Pursuant to 37 C.F.R. § 1.84(p), Figures 1A-14, 15A-15S, 23, 24, and 29A have been amended to conform to the requirements that the numbers and reference characters be plain and legible, and that the figure legends be of good quality.

The specification has been amended to conform to the numbering used in the formal drawings of the figures of the present invention.

The rejection of claims 36-39 under 35 U.S.C. § 112 (1st para.) for lack of an adequate written description is respectfully traversed in view of the amendments to claims 36-39. Specific support for the amendments of claims 36-39 are found on page 26, lines 5-10 and lines 13-16 of the specification. No new matter has been added.

The rejection of claim 38 under 35 U.S.C. § 112 (2nd para.) for indefiniteness is respectfully traversed in view of the above amendment to claim 38.

The rejection of claims 29-41, 44, and 45 under 35 U.S.C. § 101 for lack of utility is respectfully traversed.

The USPTO has based this rejection on its view that the claimed invention is not supported by either a specific asserted utility or a well-established utility. In particular, the USPTO asserts that, in order to meet the utility requirement, applicants must demonstrate “that ZmSCR transformed into a wild type plant will cause the root and hypocotyls to have increased cell divisions which cause the roots and hypocotyl of wild type plants to have increased cell layers when compared to a wild type plant not transformed with the ZmSCR nucleic acid” (February 25, 2003, Office Action, at page 5). The USPTO has also taken the position that applicants have not demonstrated that the claimed invention “will in fact increase the number of cell layers in either roots or hypocotyls of agronomically valuable plants” (*Id.*) (emphasis added). Applicants respectfully assert that these requirements are not necessary to satisfy the utility requirement of 35 U.S.C. § 101.

Under the USPTO’s Guidelines for Examination of Applications for Compliance with the Utility Requirement, “[a]n applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.” Manual for Patent Examining Procedure (“MPEP”) § 2107, at 2100-29 to 2100-30 (Rev. 1, Feb. 2003). The “specific utility” requirement requires that the specification contain a statement identifying “a specific use for or application of the invention,” as opposed to a general statement that “merely indicates that the invention may prove useful without identifying with specificity why it is considered useful.” MPEP § 2107.1, at 2100-32 (emphasis in original). A “substantial utility” defines a “real world” use, without requiring further research to identify or reasonably confirm the “real world” context of use. See MPEP § 2107.1, at 2100-32. The “credibility” requirement is “assessed from the

perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions." MPEP § 2107, at 2100-29. As discussed more fully below, applicants respectfully submit that a credible assertion of specific and substantial utility has been made for the claimed invention.

The specification states that the claimed invention can be used to "improve agronomically valuable plants" (page 24, lines 28-29). In particular, the specification shows that the isolated nucleic acid molecule of the present invention was isolated from maize (an agronomically important crop plant) and is "a gene involved in the regulation of a specific asymmetric division, in controlling gravitropic response in aerial structures, and in controlling pattern formation in roots" (page 24, lines 31-34). The specification also indicates that this isolated nucleic acid molecule may be used in constructing DNA and expression vectors (i.e., gene constructs), which are described in the specification as being useful "to alter the root and/or stem structure, and the gravitropism of aerial structures of transgenic plants" (page 26, lines 3-4). Regarding transgenic plants that overexpress the SCARECROW protein, the specification states the following:

Since *SCR* regulates root cell divisions, overexpression of *SCR* can be used to increase division of certain cells in roots and thereby form thicker and stronger roots. Thicker and stronger roots are beneficial in preventing plant lodging.

* * *

Since *SCR* affects gravitropism of aerial structures, overexpression of *SCR* may be used to develop "straighter" transgenic plants that are less susceptible to lodging.

(page 26, lines 5-9 and 12-15).

These assertions, by themselves, demonstrate a specific, substantial, and credible utility for the claimed inventions. Further, paragraph 8 of the Declaration of Philip N. Benfey Under 37 C.F.R. § 1.132 ("Benfey Declaration") (previously submitted) states that plants transformed with the *ZmSCR* gene exhibit "increased cell division in root and hypocotyl tissue, resulting in transgenic plants having thicker roots, straighter shoots, and less susceptibility to lodging than non-transgenic plants." In addition, the USPTO has acknowledged specific uses for the *ZmSCR* nucleic acid of the present invention, as stated in the February 25, 2003, Office Action:

The Examiner acknowledges that the *ZmSCR* nucleic acid can restore the wild type phenotype when transformed into

a scr mutant plant. The Examiner also acknowledges that the *ZmSCR* nucleic acid transformed into a scr mutant plant is responsible for increasing cell division in roots and hypocotyl tissue which results in transgenic plants having thicker roots than the roots of non-transformed scr mutants.

Page 4, lines 16-20. These concessions by the USPTO are completely consistent with the utility assertions made in the specification.

Even in view of the utility assertions contained in the specification and the USPTO's concessions regarding these assertions, the USPTO nevertheless maintains this utility rejection on the ground that applicants have not demonstrated transformation of "wild-type" plants. Yet, the USPTO provides no reasonable rationale or documentary evidence as to why "wild-type" transformation is necessary to show usefulness. The asserted utilities contained in the specification do not require transformation of "wild-type" plants; they only require that the transgenic plants have enhanced phenotypic characteristics compared to non-transgenic plants. By requiring a factual showing of the transformation of "agronomically important" plants with the *ZmSCR* gene of the present invention, the USPTO appears to be requiring that the invention be "marketable" for it to be useful. This view is inconsistent with Comment 4 of the USPTO's Notice of Utility Examination Guidelines, which states that marketability is not relevant in assessing an invention's utility under 35 U.S.C. § 101:

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. "[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish 'usefulness' within the meaning of § 101." In re Langer, 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974).

66 Fed. Reg. 1092, 1094 (Jan. 5, 2001).

The usefulness of the present invention is grounded, in part, in the ability of the isolated *ZmSCR* gene of the present invention to be used to enhance plants that show deficiencies in their ability to withstand lodging. There is no requirement that the starting plant be a "wild type" plant. Instead, the usefulness of the invention is borne out in a showing that transformation of a plant with the *ZmSCR* gene of the present invention can yield a plant that has thicker roots and/or is straighter than it was originally, thereby resulting

in a transgenic plant that is less susceptible to lodging than its non-transgenic counterpart. The USPTO has already acknowledged that such a showing has been made in this case.

For the reasons stated above, applicants submit that the rejection for lack of utility is not grounded in the relevant patent law and USPTO guidelines, and ignores the evidence presented in this case supporting a specific, substantial, and credible utility for the claimed invention. Thus, applicants submit that the rejection based on lack of utility is improper and should be withdrawn.

The rejection of claims 36-39 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed in view of the above amendments and following remarks. The USPTO has acknowledged that Example 3 of the specification teaches transforming *scr* mutant plants with a construct comprising the *SCR* gene operably linked to the *SCR* promoter. However, the USPTO has taken the position that the specification does not teach one of ordinary skill in the art how to use an *scr* mutant plant transformed with the *SCR* promoter::*SCR* gene construct. In support of this rejection, the USPTO rhetorically states the following: "In essence, how does one use a wild type plant generated by complementing a *scr* mutant plant with the *SCR* gene" (page 6 of the Office Action of February 25, 2003). As demonstrated below, this statement points up an apparent misunderstanding of the meaning and scope of claims 36-39.

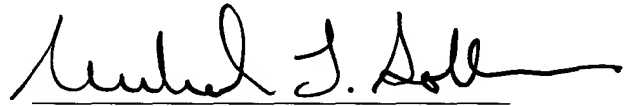
Claims 36-39 are directed to plants genetically-engineered to overexpress a SCARECROW protein or polypeptide of the present invention. The specification teaches that "overexpression of *SCR* can be used to increase division of certain cells in roots and thereby form thicker and stronger roots" (page 26, lines 5-7). The specification also teaches that, "[s]ince *SCR* affects gravitropism of aerial structures, overexpression of *SCR* may be used to develop 'straighter' transgenic plants that are less susceptible to lodging" (page 26, lines 12-15). The transgenic plant experiments described in Example 3 of the specification teach that plants transformed with the *SCR* promoter::*SCR* gene construct can be used to rescue the *scr* mutant phenotype to resemble the wild-type phenotype (page 96, line 15 to page 97, line 5). Further, the Benfey Declaration (previously submitted in this case) provides evidence that plants transformed with the *SCR* gene of the present invention "exhibit increased cell division in root and hypocotyl tissue, resulting in transgenic plants having thicker roots, straighter shoots, and less susceptibility to lodging than non-transgenic plants" (¶ 8 of the Benfey Declaration).

Contrary to the USPTO's stated position, the claimed transgenic plants are not "wild-type" plants, but rather transgenic plants that have improved phenotypic characteristics compared to counterpart non-transgenic plants. Therefore, one of ordinary skill in the art would know to plant the claimed transgenic plants where thicker roots and straighter plants are preferred. For the above reasons, applicants respectfully submit that the rejection for lack of enablement is improper and should be withdrawn.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: July 25, 2003



Michael L. Goldman
Registration No. 30,727

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1304
Facsimile: (585) 263-1600

